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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

41835 7590 11/07/2005

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/933,709	<b>Applicant(s)</b> MORRIS ET AL.	
	<b>Examiner</b> Gollamudi S. Kishore, Ph.D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The filing of RCE dated 8-29-05 is acknowledged.

Claims included in the prosecution are 18-50.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 18-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vitamin E compositions, does not reasonably provide enablement for generic 'vitamin'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Instant invention is drawn to compositions, which are free flowing. The examples indicate the use of tocopherols. Though classified under the name 'Vitamins', compounds falling under this definition have different structures and different characteristics and stabilities.

Furthermore, tocopherols used in examples are liquids as opposed to other vitamins such as A, K and B-complex vitamins and the process disclosed in the specification involves simple mixing of the components. . Applicant has not shown that the same free-flowing characteristics can be observed with all the compounds falling under 'vitamins' and which are solids.

2. Claims 18-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Composition 'is free of fatty acid esters of

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glycerine' in the independent claims lacks support in the specification as originally filed and therefore, deemed to be new matter. The examiner suggests deletion of this expression and introducing 'consisting essentially of'.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the same particle sizes for silica as recited in the parent claim 18 and therefore, not further limiting with respect to particle sizes.

It is unclear as to what applicant intends to convey by "A United States pharmacopeia, food chemical codex, or GRAS supplement" recited in claim 30.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 18-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143).

Schmidt et al. teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about 8 percent of a water insoluble carrier, about 0.2 to about 2 percent hydrophobic silica, and other ingredients (c 8, 1 15-22). Schmidt et al. further teach that the water insoluble carrier can be corn starch (c 8, line 32). Schmidt et al. also teach that the vitamin can be selected from vitamin h, D, E, K and mixtures thereof as well as vitamin B1, B6, B2, B12, C and mixtures thereof (c 2, L 20-34). Lastly, Schmidt et al. teach that the vitamin composition of their invention is suitable for the preparation of tablets (c 1, L 49).

Schmidt et al. do not teach that the vitamin is specifically mixed tocopherols. However, Schmidt et al. do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27).

Therefore, it is the position of the examiner that based upon applicant's own admission, Schmidt's teaching of vitamin E suggests the limitations of the instant claims. The reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. What is lacking in Schmidt is the claimed particle sizes of silica.

As discussed before, Schmidt 143 while disclosing free flowing, high density, fat-soluble vitamin powder preparations teaches the use of silica of bigger particle sizes (abstract, Table 1, Examples and claims).

It would have been obvious to use the silica of bigger particle sizes in the compositions of Schmidt et al 435 with a reasonable expectation of success, since as evidenced by Schmidt 143, one can still obtain free flowing, high density and stable vitamin powders.

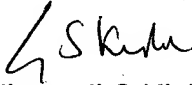
Applicant's arguments have been fully considered, but are deemed to be moot in view of the new rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK